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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,081	12/28/2001	Colin Chong	047711-0284	1999

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 10/036,081	Applicant(s) CHONG ET AL.	
	Examiner Ann Y. Lam	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 22-24, 44 and 47-54 is/are pending in the application.
- 4a) Of the above claim(s) 20, 21, 25-43, 45 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 22-24, 44 and 47-54 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: embodiment in Figure 2; embodiment in Figure 3; embodiment in Figure 4; embodiment in Figure 5; and embodiment in Figure 6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

Art Unit: 3763

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Ted Rittmaster on April 17, 2003 a provisional election was made with traverse to prosecute the invention of embodiment in Figure 2, claims 1-19, 22-24, 44 and 47-54. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-21, 25-43, 45 and 46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation in claims 16 and 54 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim 54 recites that "the inner surface of the outer layer covers the outer surface of the barrier layer only at the distal end of the catheter". However, the drawings do not show that the outer layer covers the barrier layer only at the distal end. Rather, the drawings show that the outer layer covers the barrier layer not only at the distal end, but also at a distal portion of the length of the barrier layer. Likewise, claim 16 is also not shown in the drawings for similar reasons as for claim 54.

Art Unit: 3763

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10, 13-19, 22-24, 44 and 47-54 are rejected under 35

U.S.C. 102(b) as being anticipated by Lee et al., 6,010,521.

As to claims 1, 53 and 54, Lee et al. discloses a catheter comprising a first (43) and second (42) materials defining a tubular structure ; wherein the second material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of a formulation in a catheter, see column 2, lines 37-61.

As to claim 2, the first material is disposed outside the second material, see Figure 5.

As to claim 3, the first material is disposed inside the second material, see Figure 5.

Art Unit: 3763

As to claim 4, the second material comprises a material that has a permeability index for the at least one substance that is lower than the permeability index of the outer material for the at least one substance, see column 2, lines 37-61.

As to claims 5-7, the catheter is capable of conveying CO₂, phenolic compounds, or phenol.

As to claims 8, 9, the second material comprises polytetrafluorethylene, see column 2, line 61.

As to claim 10, the second material comprises polyamide or polyetheretherketone, see column 2, lines 37-41, and column 3, lines 1-3.

As to claim 13, the first material is bio-compatible.

As to claim 14, the inner surface of the first material substantially covers an outer surface of the second material, see Figure 5.

As to claim 15, the inner surface of the first material covers only a portion of an outer surface of the second material, see Figure 5.

As to claim 16, the portion of the outer surface of the second material covered by the inner surface of the first material is located at the distal end, see Figure 5.

As to claim 17, the catheter further comprises an interior layer (63) contacting an inner surface of the second material, the interior layer comprising a substance that regulates an interaction of substances with the interior layer. The first material here is (62) and second material is (65 or 66).

As to claim 18, the substance is a hydrophilic substance, see column 5, lines 18-19.

As to claim 22, the proximal end of the catheter is capable of being connected to an implantable infusion pump.

As to claim 23, the first material is more flexible than the second material, see column 2, lines 37-61.

As to claim 24, the first material has a lower flexural modulus than the second material, see column 2, lines 37-61.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., 6,010,521, in view of Bogert et al., 6,096,012.

Lee et al. discloses the invention substantially as claimed (see above), except for the second material being diamond coated.

Bogert et al. discloses a catheter having a tip that is coated with a diamond composition (28) in order to impart to the tip a hardness, lubricity and strength necessary to penetrate skin of a patient, see column 4, lines 38-49. It would have been obvious to provide a diamond coating as taught by Bogert et al. to provide a tip on the Lee et al. catheter that is capable of penetrating skin, as would be desirable for inserting the catheter in a patient.

5. Claims 44, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., 6,010,521, in view of Polaschegg, 4,966,579.

Lee et al. discloses the invention substantially as claimed (see above), except for a pump and sensing device for regulating the delivery of the formulation.

Polaschegg discloses a catheter, pump and sensor to provide fluid delivery to a patient. It would have been obvious to provide a pump and flow sensor as taught by Polaschegg with the Lee et al. catheter to provide fluid delivery to a patient.

Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., 6,010,521, in view of Polaschegg, 4,966,579, and further in view of Bogert et al., 6,096,012.

Lee et al. in view of Polaschegg discloses the invention substantially as claimed (see above), except for the second material being diamond coated.

Bogert et al. discloses a catheter having a tip that is coated with a diamond composition (28) in order to impart to the tip a hardness, lubricity and strength necessary to penetrate skin of a patient, see column 4, lines 38-49. It would have been obvious to provide a diamond coating as taught by Bogert et al. to provide a tip on the Lee et al.-in-view-of Polaschegg catheter that is capable of penetrating skin, as would be desirable for inserting the catheter in a patient.

Art Unit: 3763

Conclusi n

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
April 17, 2003



MICHAEL J. HAYES
PRIMARY EXAMINER